

<b>BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY</b>	CRC POLICY 6.1	PAGE 1 OF 2
	PREPARED BY: J. ROWAN	
SUBJECT: Scheduling and Check-In Procedures for CRC Participants	REVIEWED BY: W. GUNTHER	
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	EFFECTIVE DATE: 10/11/04	
	REVISION HISTORY: orig. 9/5/02 rev. 10/11/04	

### **1.0 POLICY:**

The CRC Main Desk shall be notified as to the time and place of all clinical research conducted within the BNL Clinical Research Center in order to (1) post a weekly schedule of clinical research to assist with coordination and assignment of CRC staff and (2) facilitate the CRC Manager's oversight of all clinical research.

### **2.0 SCHEDULING OF CLINICAL RESEARCH:**

2.1 The Principal Investigator or his designate is responsible for notifying the CRC Main Desk that a clinical study is going to take place. This notification should take place, at minimum, 24 hours prior to commencement of the study. At the time of notification, the PI or designate should provide the CRC Main Desk (Secretary) with the following information:

- (a) the IRB number associated with the study;
- (b) the name and date of birth of the subject;
- (c) the identity of the Clinical staff member who will serve as Responsible or Participating Physician for the study;
- (d) other, specific instructions (i.e. arrival location, transportation arrangements, lunch requirements, etc.).

2.2 The CRC Secretary shall transcribe this information in the CRC Schedule Planner ("Red Book") and the CRC Weekly Calendar, posted at the Main Desk.

### **3.0 INITIATION OR RETREIVAL OF THE MEDICAL RECORD:**

3.1 The CRC Secretary, based on the information provided by the PI in Section 2.1, shall determine whether the participant has previously participated in a study at the CRC by referring to the CRC card catalog/database.

3.2 If the individual was previously a subject in another study, the CRC Secretary shall retrieve the medical chart from the CRC Medical Records library and add the appropriate paperwork associated with the new study (i.e. standing orders, consent forms, chart data forms, etc.).

3.3 If the individual is determined to be a new participant, the CRC Secretary shall assign him/her a CRC Identification number and create a chart to include the appropriate forms (i.e. standing orders, consent, chart data forms, etc) necessary for the scheduled study.

3.4 If, during the course of preparing for the study, the CRC Secretary determines that anything is not in order (i.e. designated Physician not listed on the IRB approved protocol, necessary forms not on file with CRC, etc.), the Secretary shall immediately stop preparations and inform the PI of the deficiencies. If the PI does not resolve the deficiencies, the CRC Secretary shall notify (1) the CRC Manager, (2) the Quality Assurance Physician or (3) the Office of Research Administration.

### **4.0 PARTICIPANT CHECK-IN**

4.1 Upon arrival at the CRC Main Desk, the Participant shall be greeted by the CRC Secretary who shall enter subject information (obtained from the Subject Information Form) into the database. The Secretary shall notify the responsible Physician of the Participants arrival and send the Participant for any lab test ordered by the RP. If the Participant is arriving at a satellite facility on subsequent visits, the PI shall make arrangements to insure that a Clinical Staff member is available to greet the participant.

4.2 A copy of the Participant's "Human Subject's Bill of Rights" shall be made available to every research subject.

4.3 Prior to commencement of the study, the participant shall be provided with "Informed Consent" (see PI Manual section 8.4). The Informed Consent process shall only be administered by those individuals credentialed for this specific task. Documentation supporting that the Informed Consent process took place shall be maintained in the Subject Record.

**The only official copy of this file is the one online on the Medical Department website under "Clinical Research Center Policy Manual." Before using a printed copy, verify that it is the most current version by checking the document effective date on the website.**

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**5.0 INCLUSION/EXCLUSION SCREENING PROCEDURES:** (see PI Manual section 8.5)

5.1 The Responsible or Participating Physician designated for the study shall insure that all required screenings are conducted and the results verified prior to accepting the subject into the study.

5.2 A screening is deemed required if the IRB approval research protocol states that individuals having a certain trait (i.e. sex, age, and pregnancy) are to be excluded from the research population.

5.3 Any female of child bearing age shall be given an UCG test for pregnancy.

5.4 The chart shall reflect that required screenings were conducted.